

SEP 25 2008

## Section 5 - 510(k) Summary

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<b>Submitter</b>	Johnson & Johnson Healthcare Products, Division of McNeil – PPC, Inc. 199 Grandview Road Skillman, NJ 08558
<b>Contact</b>	Nader Fotouhi, Ph.D. Manager, Regulatory Affairs J&J Consumer & Personal Products Worldwide 199 Grandview Road Skillman, NJ 08558 Phone: (908) 904-3730 Fax: (908) 904-3748
<b>Date</b>	April 29, 2008
<b>Trade Name</b>	K-Y® Brand Intrigue™ 2-in-1 Massage Crème™
<b>Common Name</b>	Personal Lubricant
<b>Classification Name</b>	NUC – condom compatible personal lubricant
<b>Statement</b>	This proposed device is substantially equivalent to predicate device, K-Y® Brand Touch Massage™ 2-in-1 Warming® body massage + Personal lubricant.
<b>Device description</b>	This device is developed for non-therapeutic body massage and personal lubricant compatible with latex condom that imparts a warming sensation upon the skin.
<b>Intended use</b>	The intended use of this device is as a non-therapeutic body massage and personal lubricant compatible with latex condom.

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[INFORMATION IN BRACKETS IS CONSIDERED CONFIDENTIAL]

## 510(k) Summary of Safety and Effectiveness (Continued)

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<b>Indications statement</b>	This device and predicate device have similar indications, by being applied to the vaginal area or a condom in order to enhance comfort and ease of intimate activity. They may also be used as a non-therapeutic body massage product.
<b>Technological characteristics</b>	The proposed device has the same technological characteristics as currently marketed condom compatible personal lubricants.
<b>Performance data</b>	<p>The results from laboratory testing, pre-clinical evaluations and testing, and human use show that the proposed device performs equivalently to the predicate devices. Laboratory test results demonstrated that the proposed device is compatible with the leading commercial brands of latex condoms and provides lubricity for use as a personal lubricant.</p> <p>The pre-clinical evaluation and testing as well as human use data show that the proposed device is safe for use as a personal lubricant.</p>
<b>Conclusion</b>	The proposed device is substantially equivalent to the currently marketed products in technology, intended use, safety, and suitability characteristics.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 25 2008

Nader Fotouhi, Ph.D.  
Manager, Regulatory Affairs  
McNeil-PPC, Inc.  
Consumer Healthcare Products  
199 Grandview Road  
SKILLMAN NJ 08558

Re: K081236  
Trade Name: K-Y® Brand Intrigue™ 2-in-1 Massage Crème  
Regulation Number: 21 CFR 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: September 17, 2008  
Received: September 18, 2008

Dear Dr. Fotouhi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Joyce M. Whang, Ph.D.  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Section 4 - Indications for Use Statement

510(k) Number, if known

K 081236

Device Name: K-Y® Brand Intrigue™ 2-in-1 Massage Crème™

Indications for Use:

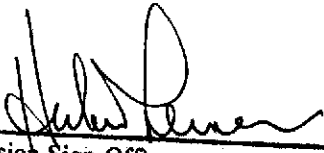
K-Y® Brand Intrigue™ 2-in-1 Massage Crème™ is a personal lubricant, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

This product is compatible with latex condoms.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-the-Counter Use X \_\_\_\_\_

  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K 081236